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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	)Group Art Unit: 1655
Peter Iwen et al.	)Examiner: J. Goldberg
Serial No. 09/580,797	)Response to Paper No.: 11
Filed: May 30, 2000	)
For: "MATERIALS AND METHODS FOR MOLECULAR DETECTION OF CLINICALLY RELEVANT PATHOGENIC FUNGAL SPECIES"	)

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August 6, 2001
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Jane C. Bogan

RESPONSE TO RESTRICTION REQUIREMENT

In response to the restriction requirement set forth in the July 5, 2001 Official Action, please amend the above-identified patent application as follows:

In the claims:

Please add new claim 19:

19. (New) A method for determining whether one or more Aspergillus ssp. is present in a biological sample, said method being selected from the group consisting of:

a) comparing the sequence of nucleic acid in the sample with nucleic acid sequences from the non-pathogenic and pathogenic species of Aspergillus fungus to determine which species is responsible for infection in the patient; or

b) using DNA restriction mapping to compare the restriction pattern produced when a restriction enzyme cuts a sample of nucleic acid from the sample as compared with the restriction pattern obtained from pathogenic and non-

pathogenic species of Aspergillus fungus, or,

c) using a specific binding member capable of binding to a either the pathogenic nucleic acid sequence, the specific binding member comprising nucleic acids which distinguish between fungal species based on hybridization specificities, or substances comprising an antibody domain with specificity for a pathogenic or non-pathogenic fungal nucleic acid sequence, the specific binding member being labeled so that binding of the specific binding member to its binding partner is detectable; or

d) in situ hybridization between fungal DNA from permeabilized tissue sections and fluorescent molecular probes specific for pathogenic fungal species under investigation; or

e) using PCR involving one or more primers based pathogenic fungal gene sequences to screen for the presence of the pathogenic species in a sample, wherein the methods of steps a)- e) comprise the use of nucleic acids having the sequence of SEQ ID NOS: 3, 4, 5, 6, 7, or 8.

Please cancel claims: 1, and 6-18.

REMARKS

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated July 5, 2001 in the above-identified patent application. It is the Examiner's position that claims 1-18 in the present application are drawn to nine (9) patentably distinct invention which are as follows:

Group I: Claims 1, 15-18 drawn to a universal primer set for application of a target DNA sequence associated with pathogenic strains of fungi and kits containing the same;

Group II: Claims 2-5, drawn to a method for determining whether one or more fungal species is present in a sample;

Group III: Claims 6 and 11, drawn to an oligonucleotide sequence specific for Penicillium spp. comprising SEQ ID NO:

25 and an oligonucleotide sequence specific for Penicillium marnefeii comprising SEQ ID NO: 30;
Group IV: Claim 7, drawn to an oligonucleotide sequence specific for Malbranchia spp. comprising SEQ ID NO: 26;
Group V: Claim 8, drawn to an oligonucleotide sequence specific for Arthorgrothilus spp. comprising SEQ ID NO: 27;
Group VI: Claim 9, drawn to an oligonucleotide sequence specific for Cylindrocarpon destructans comprising SEQ ID NO: 28;
Group VII: Claim 10, drawn to an oligonucleotide sequence specific for Sporothrix schenkii comprising SEQ ID NO: 29;
Group VIII: Claim 12, drawn to an oligonucleotide sequence specific for Coccidiodes immitis comprising SEQ ID NO: 31; and
Group IX: Claims 13 and 14 drawn to an oligonucleotide sequence specific for Candida tropicalis comprising SEQ ID NO: 32 and an oligonucleotide specific for Candida parapsilosis comprising SEQ ID NO: 33.

Applicants respectfully traverse the restriction between the groups I, III, IV, V, VI VII VIII and group IX inventions. A withdrawal or modification of the restriction requirement is clearly in order for the reasons set forth below.

According to the MPEP §803.01, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the inventions must be independent and distinct as claimed and 2) there must be a serious burden on the Examiner if the restriction is not required. Applicants respectfully submit that the methods of claims 2-5 entail the use of subsets of the oligonucleotide sequences set forth in SEQ ID NOS: 1-33 in order to identify the fungal species specified by the claim. As such, the position that each oligonucleotide sequence claimed comprises an independent invention is improper. Additionally, the oligonucleotide sequences claimed consist of discrete sequences of a specified length. Given the electronic searching capacity of the United States Patent and Trademark Office, it cannot be reasonably

maintained that searching 39 oligomers comprises a serious searching burden.

Moreover, it is improper to require restriction between all of the nucleotide sequences in the present application, *i.e.*, between Groups I, and III-IX. According to the M.P.E.P. § 803.04,

> ... to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to ... permit a reasonable number of such nucleotide sequences to be claimed in a single application. *See* Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).
>
> It has been determined that normally **ten sequences constitute a reasonable number for examination purposes**. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. (*Emphasis added; see also M.P.E.P. § 2434.*)

Therefore, under restriction practice as it applies to applications filed under 35 U.S.C § 111(a), a nine way restriction should not have been required between the claims directed to the less than 40 oligonucleotides encoding fungal specific primers in this case. In light of the foregoing, Applicants respectfully request modification of the restriction requirement set forth in the Official Action dated July 5, 2001.

In order to be fully responsive however, Applicants hereby elect the claims of the group II invention for prosecution at this time. The Examiner also asserts that the because claim 2 reads on different fungal species, Applicants must elect a single genus of fungi for detection for examination purposes at this time. Applicants hereby elect

Aspergillus ssp. for examination purposes at this time. It is Applicants understanding that if methods for identifying Aspergillus ssp. are found allowable, claims to methods for identifying the unelected fungal species will then searched by the Examiner for inclusion in the present application. Confirmation of Applicants understanding in this regard in the next office action will be greatly appreciated.

Applicants reserve the right to file one or more continuing applications under 35 U.S.C. §120 on the subject matter of any claims finally held withdrawn from consideration in this application.

New claim 19 is presented directed to additional methods for identifying Aspergillus ssp. in a biological sample. Support for new claim 19 can be found at page 15, line 22 over to page 16, line 14 and in the addendum to the application listing the sequences claimed at pages 35 and 36.

Favorable consideration leading to prompt allowance of the present application is respectfully requested.

Respectfully submitted,
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